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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/432,881	MARKEY ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14-26,32-34,47-55 and 97-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-26,32-34,47-55 and 97-151* is/are rejected.

7)☒ Claim(s) *99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **1/29/07** presents remarks and arguments to the office action mailed **8/03/06**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1-9, 14-26, 32-34, 47-55 and 97-151 are pending. Claims 10-13, 27-31, 35-46 and 56-96 are cancelled. Examiner notes the claims with the status identifier indicating "new" are not newly added but were previously submitted.

Claim Objections

Claim 99 is objected for the following informalities: There should be a space between "98" and "in". Appropriate correction is required.

New *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 14-26, 32-34, 47-55 and 97-151 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", in claims 8-9, 17-18, 21-22, 25-26, 33-34, 102-104, 114-115, 119-120, 128-129, 132-133, 137-138 and 141-142 is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about"(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about".

The term "size sufficiently large " in claims 1-9, 14-26, 32-34, 47-55 and 97-151 is a relative term which renders the claim indefinite. The term "size sufficiently large" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what size the composition would be considered as having " a size large enough" for the recited desired properties. Without specifically stating what is meant by the term "a size large enough" in the instant specification, any particle size of the composition is considered as "sufficiently large enough" to achieve the herein claimed properties.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 99 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the fed mode inducing agent is sufficiently potent that onset of said fed mode results from release of an amount of said fed mode inducing agent that is less than 500 mg. The claim fails to show steps that resulted in this calculation of released drug of the fed mode inducing agent. See the last two lines of claim 99.

Applicant argues that no calculation is necessary and the rejection is not fully understood.

Claim 99 recites the fed mode agent is sufficiently potent that onset of said mode results from release of an amount of said fed mode inducing agent that is less than 500 mg. There must have been a way/method of determining how much of the fed mode is released at onset. How was the amount release determined?

The rejection is maintained.

Claim Rejections - 35 USC § 102 (The rejections below is reinstated from office action dated 11/28/05.

In the prior Office Action,, Examiner withdrew the rejection; however, upon careful review, taking into consideration that intended use is given no patentable weight, the rejection is reintroduced below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 –6, 14-18, 47-48,105-107 and 143-144 are rejected under 35 U.S.C. 102(b) as being anticipated by MacKenizie et al., Fundamental and Applied toxicology.

MacKenzie et al. disclose reduction of body weight/mass in individuals receiving the instant active agents (alkali and alkaline earth metal docusates) in claims 1 (b) and 14-18. (See abstract). Dioctyl sulfosuccinate is known as docusate sodium). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The instant claims 1, and 14-18 require administration of specific levels of active ingredient (see page 54, left column, second ¶, underlined section, and also at page 54, right hand col., under diet preparation, underlined). MacKenize discloses the active agent is present at 0.1, 0.5 or 1.0 %, calculated to be 1000 mg as the purity of the active metal docusate is 99.4% (see section Methods) which meets the limitation(s) of the claims. The properties, as recited in claims 2-6, 47-48, 105-107 and 143-144, will inherently be present in the compound. Thus the claims are anticipated as no patentable weight is given to use or function.

In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior

art are the same, the applicant has the As stated in the MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established".

Claims 1-6,14-18 and 47-48,105-107 and 143-144 are rejected under 35 U.S.C. 102(b) as being anticipated by Kais et al., US Patent 5,516,524 ('524).

The '524 patent discloses methods of treating constipation in human subjects by administering to said human a laxative composition (drug), dioctyl sulfoccinate (DSS), (fed mode agent) and the solid matrix-a bulk fiber methylcellulose (see abstract and also col. 7, lines 5-10), i.e., the solid matrix and, therefore, anticipates the claim since the specification at pages 6-7 discloses there is no definition of a solid matrix. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

The reference also discloses a dose of about 200 mg to 300 mg of sodium or calcium docusate (see abstract, col. 9-11, col. 13, lines 34-45, col. 14, lines 15-46) in current claims 14-18. The method steps of '524 are the same as the instant claims. Kais discloses administration of docusate metals to human patients, which is the same population as those instantly claimed. '524 discloses the use of docusate metals in the same dosing range as the instant claims. Relieving constipation induces at least a degree of fed mode within the scope of the instant claims. Since the disclosure of '524 meets all elements of the instant claims, this method also inherently anticipates the intended use of the instant claims. The properties, as recited in claims 2-6, 47-48, 105-107 and 143-144, will inherently be present in the compound. Thus the claims are anticipated as no patentable weight is given to use or function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 14-26, 32-34, 47-55, 97-104, 105-110, 112, 116-124, 130 and 143-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., US 6,120,803, taken with MacKenizie et al., Fundamental and Applied toxicology , in view of Hagen et al., PNAS, Shaffer et al., American Society of clinical Nutrition and Pupovac et al., J. Nutrition.

Wong et al. teach an active dosage form retained in the stomach for prolonged delivery, wherein the polymer matrix swells in the stomach (see abstract), wherein the compound is arginine (see col. 6, line 17), as in claims 1, 3, 32 105 and 130, item e, an alkaline, such as sodium salts (see col. 6, lines 22-26), as in the instant claims 1 and 105 item b, wherein the composition is retained in the a solid matrix with said drug in a sustained manner (see col. 5, lines 28-42 and col. 6, lines 32-41), as in claims 2 and 106, wherein said mode inducing agent is separate from the solid matrix. The fed mode agent is arginine (see col. 6, line 17) and is separate from the solid matrix-a polymer matrix (see col. 5, line 28-31) of claims 4 and 108. The size of the solid matrix is sufficiently large to promote retention. See col. 5, lines 55-67. Soluble polymers react with liquid and swell to more than twice their size and are known to one of ordinary skill in the art a common characteristic, as required by claims 5-6 and 109-110. Also see col. 9, lines 44-45. As to claim 97 and 143, see the abstract where the first solid matrix is disclosed (see col. 2, lines 58-67 and col. 7, lines 17-25) and wherein the composition comprises a common single matrix (see col. 7, lines 17-19), as in claim 98. As to the dosage of arginine in claims 32-34, Wong teaches (see col. 21, lines 34-47) the active agent is in a dosage form of 200 mg. Arginine is the active form. Thus the dosage is within the claim limitations of claims 32-33. With regard to claim 34, the dosage amount is within the purview of the skilled artisan to optimize and as taught by Wong et al. using the term "if" suggests that these dosage forms vary depending on administration factors (see col. 21, lines 34-47).

With regard to claims 47-48, 52, and 143-144, osmotic pressure is disclosed in col. 6, lines 59-67. The matrix is of cellulose polymer, hydroxymethylcellulose; the matrix is water soluble; and the water soluble matrix is cellulosic, sodium carboxymethylcellulose (see col. 5, lines 55-67), as in claims 49-55, 145-147, 149-151. The reference also teaches the fed mode agent is a sugar alcohol-mannitol (see col. 6, line 14), as in claim 112.

The instant claims differ in that the reference does not teach or suggest the fed inducing agent resides in a surface coating or layer on said solid matrix permitting substantially immediate release, as required by instant claims 3 and 107. However, Wong teaches these agents are in a solid matrix (see col. 7, lines 17-33) wherein the fed mode inducing agent is a unitary compressed dispersion of a solid active agent in a gel forming erodible polymer and may contain a gastric emptying delaying agent that increases the retention time of the dosage form in the stomach. As explained above, the active agent arginine meets the limitation of fed mode reducing agent of claim 1. Since the gastric emptying delaying agent may be combined in the composition with the active agent for local delivery to the environment of use, it may be coated on the dosage form to provide the desired physiological response (see col. 7, lines 28-32). Therefore, it resides in a surface coating and when in the stomach, the gastric fluid will cause the bonds of the polymer to break as swelling leads to the formation of very lose particles and prolonged retention of the solid matrix with a substantial release. Note that "substantially" has been determined to be any amount.

Mackenzie is applied here as above.

Hagen et al. teach administration α-lipoic acid to mammals as a satiety composition, as recited in instant claims 23-24 and 123-124, because α-lipoic acid has been used in the past in satiety compositions.

Shaffer et al. teach the effects of xylitol (sugar alcohol) calorie intake on gastric emptying, (see abstract), thereby meeting the limitations of claims 112-115.

Pupovac et al. teaches β-casomorphin affects food intake by delaying of gastric emptying, an obvious variation to claims 19-20, and 121-122, due to the combination of these drugs (β-casomorphin and xylitol).

One of ordinary skill in the art would have been motivated to combine the above cited prior art and formulate a pharmaceutical composition that is used for promoting the fed mode of a patient in need thereof, as the compounds cited have been used either singularly or in combination to promote satiety.

Thus, at the time of filing this application, one of ordinary skill in the art would have found the instant pharmaceutical composition obvious over the combined references. The references teach a fed mode inducing agent(s) for the claimed invention. The references are relied upon here because they have conveyed all of the claimed limitations for one of ordinary skill in the art. Accordingly, one of ordinary skill in the art would thus have been motivated to prepare said pharmaceutical composition with a reasonable expectation of success in doing so because the teachings are to a pharmaceutical agent with a prolonged release agent for gastric retention with a swellable dosage matrix. The polysoluble polymers are the same as those of the

claimed invention. The skilled artisan would expect compounds of close structural similarities to possess similar properties.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
9/19/07

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER